DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

- 3723. Misbranding of dextro-amphetamine sulfate tablets, methamphetamine hydrochloride tablets, and diethylstilbestrol tablets. U. S. v. Frank Schwilk (Schwilk's Pharmacy). Plea of nolo contendere. Fine, \$300. (F. D. C. No. 31283. Sample Nos. 84692-K, 10862-L, 11057-L, 11663-L, 11953-L.)
- Information Filed: On or about January 21, 1952, Southern District of Ohio, against Frank Schwilk, trading as Schwilk's Pharmacy, at Dayton, Ohio.
- INTERSTATE SHIPMENT: From the States of Pennsylvania, Illinois, and Indiana, into the State of Chio, of quantities of dextro-amphetamine sulfate tablets, methamphetamine hydrochloride tablets, and diethylstilbestrol tablets.
- ALLEGED VIOLATION: On or about December 18, 1950, and January 5 and 16 and February 7 and 8, 1951, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), a portion of the dextro-amphetamine sulfate tablets and a portion of the repackaged methamphetamine hydrochloride tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (f) (2), all of the methamphetamine hydrochloride tablets failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

- DISPOSITION: April 24, 1952. A plea of nolo contendere having been entered, the court imposed a fine of \$300.
- 3724. Misbranding of sulfadiazine tablets, thyroid tablets, conjugated estrogen tablets, and dextro-amphetamine sulfate tablets. U. S. v. Central Drug Co., Oscar W. Howser, and Allen T. Howser. Pleas of guilty. Central Drug Co. fined \$200, Oscar W. Howser fined \$100, and Allen T. Howser fined \$50. (F. D. C. No. 32702. Sample Nos. 72175-K, 11292-L, 11626-L, 11646-L.)
- Information Filed: April 2, 1952, Southern District of Ohio, against the Central Drug Co., a corporation, Steubenville, Ohio, Oscar W. Howser, pharmacist and president of the corporation, and Allen T. Howser, pharmacist and secretary-treasurer of the corporation.
- INTERSTATE SHIPMENT: Prior to the dates of the sales, various quantities of sulfadiazine tablets, thyroid tablets, conjugated estrogen tablets, and dextro-amphetamine sulfate tablets were shipped in interstate commerce into the State of Ohio.
- ALLEGED VIOLATION: On January 12, 1950, and May 3, 23, and 24, 1951, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were caused to be repacked and sold without a physician's prescription.

^{*}See also No. 3721.

The Central Drug Co. was named as a defendant in all counts of the information, and, in addition, Oscar W. Howser was joined as a defendant in two of the counts and Allen T. Howser was joined as a defendant in one of the counts and charged with the violations involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the drugs failed to bear labels containing accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (f) (2), the labeling of the *sulfadiazine* tablets failed to bear adequate warnings against use of the drug in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

- Disposition: April 8, 1952. Pleas of guilty having been entered, the court imposed a fine of \$200 against the corporation, \$100 against Oscar W. Howser, and \$50 against Allen T. Howser.
- 3725. Misbranding of Combisul-TD tablets, thyroid tablets, and sulfathiazole tablets. U. S. v. Irvin J. Kalt (Kalts Drugs). Plea of nolo contendere. Fine, \$300. (F. D. C. No. 30621. Sample Nos. 84934-K, 85057-K, 85058-K.)
- INFORMATION FILED: November 26, 1951, Southern District of Ohio, against Irvin J. Kalt, trading as Kalts Drugs, Dayton, Ohio.
- ALLEGED SHIPMENT: On or about August 11 and December 12, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing accurate statements of the quantity of the contents; and, Section 502 (f) (2), the labels of the repackaged drugs failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

Further misbranding, Section 502 (b) (1), the repackaged sulfathiazole tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (e) (2), the repackaged Combisul-TD tablets failed to bear a labed containing the common or usual name of each active ingredient of the tablets; and, Section 502 (f) (1), the labeling of the repackaged Combisul-TD tablets and thyroid tablets failed to bear adequate directions for use.

- Disposition: April 24, 1952. A plea of nolo contendere having been entered, the court imposed a fine of \$300.
- 3726. Misbranding of pentobarbital sodium capsules. U. S. v. Red Star Pharmacy, Inc. (J. F. Epstein Drugs), and Jerome F. Epstein. Pleas of guilty. Fine of \$100 against individual and \$1 against corporation. (F. D. C. No. 31299. Sample No. 4851-L.)
- Information Filed: April 3, 1952, District of Massachusetts, against Red Star Pharmacy, Inc., trading as J. F. Epstein Drugs, Boston, Mass., and Jerome F. Epstein, president-treasurer of the corporation.